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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/722,119

11/25/2003

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EXAMINER

COMSTOCK, DAVID C

ART UNIT

PAPER NUMBER

3733

MAIL DATE

DELIVERY MODE

10/04/2007

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

9

Office Action Summary	Application No. 10/722,119	Applicant(s) MALEK, MICHEL H.	
	Examiner David Comstock	Art Unit 3733	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 30 August 2007.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☐ Claim(s) 1-25 and 43 is/are pending in the application.
- 4a) Of the above claim(s) 3 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1, 2, 4-25 and 43 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 25 November 2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date <u>4/04, 8/05</u> | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Election/Restrictions

Applicant's election without traverse of species I, Fig. 1, claims 1, 2, 4-25 and 43, in the reply filed on 30 August 2007 is acknowledged. Applicant's indication that claims 1 and 21 are generic and that Fig. 10 is another view of the embodiment of Fig. 9 is likewise acknowledged. Claims 26-42 and 44 were canceled by Applicant and claim 3 is withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected species, there being no allowable generic or linking claim.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 6 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In claim 6, the socket referred to lacks antecedent basis in claim 1. For examination purposes, claim 6 will be considered as if it depended from claim 5.

Appropriate correction is required.

Claim Rejections - 35 USC § 101

Claims 1, 2 and 4-20 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter. Claim 1 recites part of the human body in combination with the device, i.e. positively claiming the entirety of: "a disc prosthesis or a disc nucleus replacement disposed between two adjacent vertebrae in the spinal column". Similarly, claim 17 positively claims: "one or more prosthetic vertebral bodies disposed within the spinal column". It has been held that a claim directed to or including within its scope, a human being will not be considered to be patentable subject matter under 35 U.S.C. 101. The grant of a limited, but exclusive property right in a human being is prohibited by the constitution. *In re Wakefield*, 422 F.2d 897, 164 USPQ 636 (CCPA 1970). For examination purposes, claims 1 and 17 will be considered as if the limitations involving the combination with a human were not present.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 2, 4-12, 16-25 and 43 are rejected under 35 U.S.C. 102(b) as being anticipated by Alby (6,241,730).

Alby discloses the claimed invention including a stabilizing element comprising first and second segments, e.g., 4A, 4B connected by a pivoting joint, e.g., 4 (see, e.g.

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Fig. 1-3). Connectors such as bone screws (not shown) are adapted to connect the stabilizing element to vertebra (see col. 2, line 67). The segments comprise a pin style ball and socket connection comprising damping elements, e.g., 12 around a neck. A flat strip 11 extends around a midsection. The joint comprises opposing concave and convex surfaces (e.g. lateral edges of the strip and the surface opposing convex ball end of pin 4Ba). Opposing threads can be characterized as windows and tabs, as they define openings or windows to their minor diameter and small extensions or tabs to their major diameter (see, e.g., Fig. 3).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 13 and 14 are rejected under 35 U.S.C. 103(a) as being unpatentable over Alby (6,241,730) in view of Crozet et al. (6,217,578).

Alby discloses the claimed invention except for explicitly reciting the use of cross-connectors. Crozet et al. disclose a system for treating vertebrae comprising the use of cross-connectors to "provide enhanced stability" to other spinal systems and improve the treatment of the spine (see, e.g., col. 7, lines 29-36). It would have been obvious to one having ordinary skill in the art at the time the invention was made to provide the intervertebral link device of Alby with a cross-connector, in view of Crozet et al., in order

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to provide enhanced stability to the device of Alby and improve the treatment of the spine. It is noted that the use of a cross connector on single ends of the device set forth by Alby would provide the advantage of additional stability as taught by Crozet, while still allowing for relative motion with respect to the other ends of the device of Alby. Moreover, it is predictable that both of these known systems would be combined for their stated purposes and advantages (reduced mechanical stresses and enhanced stability).

Claim 15 is rejected under 35 U.S.C. 103(a) as being unpatentable over Alby (6,241,730) in view of Karpman et al. (6,214,012).

Alby discloses the claimed invention except for explicitly reciting the use of a tissue growth-resistant material. Karpman et al. teach that bone cement can be used to enhance the fixation of screws in bone (see, e.g., col. 9, lines 28-44). Therefore, it would have been obvious to a person having ordinary skill in the art to install the screws of Alby with bone cement, in view of Karpman et al., in order to enhance the fixation of the screws in bone and reduce the chance of them coming loose. (Bone cement is a tissue growth-resistant material as evidenced by McLeer, US 2006/0079895 A1, paragraph 46. It is noted that a person having ordinary skill in the art would have been motivated to use bone cement for the reason provided by Karpman et al.; McLeer simply evidences that bone cement meets the limitation in Applicant's claim regarding the use of a substance that inhibits tissue growth.) Moreover, it also would have been obvious to have provided the device of Alby with a tissue growth-resistant material, since it has been held to be within the general skill of a worker in the art to select a known material on the basis of its suitability for the intended use as a matter of obvious design choice. *In re Leshin*, 125 USPQ 416.

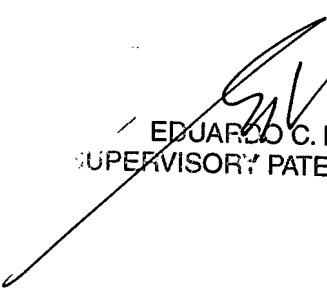
Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David Comstock whose telephone number is (571) 272-4710. Please leave a detailed voice message if examiner is unavailable. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Eduardo Robert can be reached at (571) 272-4719. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



D. Comstock



EDUARDO C. ROBERT
SUPERVISORY PATENT EXAMINER